K083231

SECTION 5 – 510(k) SUMMARY

JAN 2 6 2009

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Date Prepared:	September 23, 2008
Trade Name(s):	Panthera Mechanical Wheelchairs Models S2, U2, Bambino, Micro and BT
Common/Usual Name:	Mechanical Wheelchair
Classification Name:	Wheelchair, Mechanical
Classification Number:	890 3850
Classification Panel:	Physical Medicine Devices
CDRH Product Code:	IOR
Regulatory Class:	I

Section 5 1 – Device Description

Panthera mechanical wheelchairs are manually driven, lightweight, performance type of wheelchairs that have been designed and developed to be used in both

indoor and outdoor environments, and to transport one (1) person at a time These wheelchairs are made available by Panthera Production AB in five (5) different top-level models, with each model designed for a specific end-user application The five different models of chairs are the

- S2
- U2
- Bambino
- Micro
- BT

There are no basic differences in the general construction of each model wheelchair frame, or the materials and components used to make them The Chassis are made form chrome-molly steel, while their Pushrims and Footrests are made from a titanium alloy Wheels are of a spoke and hub design using metal components and rubber tires, while the casters are of a semi-solid polymer base design The seat cushion and back are made from flame retardant polyurethane coated polyester fabric, over a foam core The primary differences in the models of wheelchairs are in their dimensions, gross weights, weight carrying capacities, adjustability features, wheels, accessories and hardware options

Section 5 2 – Intended Use

Panthera mechanical wheelchairs are manually operated multifunctional wheelchairs designed for indoor/outdoor use and intended to provide mobility to persons that have the capability of operating a mechanical wheelchair

Section 5 3 – Predicate Devices

5 3 1 - Invacare Top End Terminator Titanium wheelchair (ref K012167)
5 3 2 - Invacare Top End Terminator SS wheelchair (ref K990157)

Section 5 4 – Safety and Effectiveness

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics But, it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device

As such, it has been shown in this 510(k) submission, that the differences between the Panthera mechanical wheelchairs and the predicate devices, the Invacare Top End Terminator Titanium wheelchair (ref K012167) and the

Invacare Top End Terminator SS wheelchair (ref K990157) (K051387), do not raise any questions regarding their safety and effectiveness

Panthera mechanical wheelchairs as designed and manufactured are as safe and effective as the predicate devices and therefore are determined to be substantially equivalent to the referenced predicate devices

Section 5 5 – Performance Data

Panthera mechanical wheelchairs have been designed, manufactured and tested for conformance to the applicable ISO and EN standards as referenced in this submission In addition, Panthera mechanical wheelchairs passed all required consensus standards testing for conformance to the FDA's *Guidance Document for the Preparation of Premarket Notification [510(K)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 6 2009

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Austin, Texas 78746

Re K083231

Trade Name Panthera Mechanical Wheelchairs Models (S2, U2, Bambino, Micro and BT)
Regulation Number 21 CFR 890 3850
Regulation Name Mechanical wheelchair
Regulatory Class I
Product Code IOR
Dated September 30, 2008
Received November 5, 2008

Dear Mr Goldman

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson

Mark N Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name

Panthera Mechanical Wheelchairs

Models (S2, U2, Bambino, Micro and BT)

Indications for Use

Panthera mechanical wheelchairs are manually operated multifunctional wheelchairs designed for indoor/outdoor use and intended to provide mobility to persons that have the capability of operating a mechanical wheelchair

Prescription Use _____X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083231